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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/530,217	03/30/2005	Yusuke Nakamura	082368-003910US	1888

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TOWNSEND AND TOWNSEND AND CREW, LLP
TWO EMBARCADERO CENTER
EIGHTH FLOOR
SAN FRANCISCO, CA 94111-3834

EXAMINER	
HOLLERAN, ANNE L	
ART UNIT	**PAPER NUMBER**
1643	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	04/24/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,217	NAKAMURA ET AL.	
	Examiner	Art Unit	
	Anne L. Holleran	1643	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) 1-32 is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) 1-32 are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claim(s) 1, and 30 (to the extent claim 30 is drawn to a pharmaceutical composition comprising a polypeptide), drawn to a polypeptide, and a pharmaceutical composition thereof where the polypeptide comprises the amino acid sequence of SEQ ID NO: 16, or comprises the amino acid sequence of SEQ ID NO: 16 with substitutions, deletions, insertions or additions, or a polypeptide encoded by a polynucleotide that hybridizes under stringent conditions to a polynucleotide consisting of the nucleotide sequence of SEQ ID NO: 15.

Group II, claim(s) 2-5, 7 and 30, (to the extent claim 30 is drawn to a pharmaceutical compositions comprising a polynucleotide), drawn to an isolated polynucleotide encoding the polypeptide of claim 1, a vector comprising the polynucleotide, a host cell comprising the polynucleotide or vector, and to a method for producing the polypeptide of claim 1.

Group III, claim(s) 6, 20, 22 (to the extent claim 22 is drawn to a composition comprising the antibody) drawn to an antibody that binds to a polypeptide of claim 1, and compositions thereof.

Group IV, claim(s) 8-10, 19, 21-23, (to the extent claim 22 is drawn to composition comprising the antisense polynucleotide or small interfering RNA), 25 (to the extent the method uses a compound that is an antisense polynucleotide or small interfering RNA), 26 (to the extent the method is dependent from claim 23) and 31, drawn to antisense or small interfering RNA against the polynucleotide of claim 2, and to methods of use.

Group V, claim(s) 11, 12 and 18 (to the extent claims 11 and 18 comprise methods of detecting mRNA encoding SEQ ID NO: 16), drawn to methods for diagnosing a cell proliferative disease.

Group VI, claim(s) 11, 12 and 18 (to the extent claims 11 and 18 comprise methods of detecting a protein comprising SEQ ID NO: 16), drawn to methods for diagnosing a cell proliferative disease.

Group VII, claim(s) 11, 12 and 18 (to the extent claims 11 and 18 comprise methods of detecting the biological activity of a protein comprising SEQ ID NO: 16), drawn to methods for diagnosing a cell proliferative disease.

Group VIII, claim(s) 13, 15, 16 and 18, drawn to methods for screening for compounds for treating cell proliferative disease, comprising contacting a test compound with a polypeptide that comprises the amino acid sequence of SEQ ID NO: 16, or comprises the amino acid sequence of SEQ ID NO: 16 with substitutions, deletions, insertions or additions, or a polypeptide encoded by a polynucleotide that hybridizes under stringent conditions to a polynucleotide consisting of the nucleotide sequence of SEQ ID NO: 15.

Group IX, claim(s) 14 and 18, drawn to a method for screening for a compound for treating a cell proliferative disease, comprising contacting a candidate compound with a cell expressing a polynucleotide comprising the sequence of SEQ ID NO: 15.

Group X, claim(s) 17 and 18, drawn to methods of screening for a compound for treating a cell proliferative disease, comprising the steps of contacting a candidate compound with a cell into which a vector comprising the transcriptional regulatory region of a marker gene and a reporter gene that is expressed under the control of the transcriptional regulatory region has been introduced, where the marker gene comprises SEQ ID NO: 15.

Group XI, claim(s) 24-26 (claim 25, to the extent the compound is an antibody) and 32, drawn to methods for treating a cell proliferative disease, comprising administering an antibody that binds a polypeptide that comprises the amino acid sequence of SEQ ID NO: 16, or comprises the amino acid sequence of SEQ ID NO: 16 with substitutions, deletions, insertions or additions, or a polypeptide encoded by a polynucleotide that hybridizes under stringent conditions to a polynucleotide consisting of the nucleotide sequence of SEQ ID NO: 15.

Group XII, claim(s) 25 and 32, drawn to methods for treating a cell proliferative disease, comprising administering a compound selected from the method of 17.

Group XIII, claim(s) 25 and 32, drawn to methods for treating a cell proliferative disease, comprising administering a compound selected from the method of 14.

Group XIV, claim(s) 27, drawn to methods for treating or preventing cancer comprising the step of administering a polypeptide that comprises the amino acid sequence of SEQ ID NO: 16, or comprises the amino acid sequence of SEQ ID NO: 16 with substitutions, deletions, insertions or additions, or a polypeptide encoded by a polynucleotide that hybridizes under stringent conditions to a polynucleotide consisting of the nucleotide sequence of SEQ ID NO: 15.

Group XV, claim(s) 27, drawn to methods for treating or preventing cancer comprising the step of administering a polynucleotide that encodes a polypeptide that comprises the amino acid sequence of SEQ ID NO: 16, or comprises the amino acid sequence of SEQ ID NO: 16 with substitutions, deletions, insertions or additions, or a polypeptide encoded by a polynucleotide

that hybridizes under stringent conditions to a polynucleotide consisting of the nucleotide sequence of SEQ ID NO: 15.

Group XVI, claim(s) 28 and 29, drawn to methods for treating or preventing cancer comprising the step of contacting a polypeptide with antigen presenting cells, where the polypeptide comprises the amino acid sequence of SEQ ID NO: 16, or comprises the amino acid sequence of SEQ ID NO: 16 with substitutions, deletions, insertions or additions, or a polypeptide encoded by a polynucleotide that hybridizes under stringent conditions to a polynucleotide consisting of the nucleotide sequence of SEQ ID NO: 15.

The inventions listed as Groups I-XVI do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons: the feature that is common to groups I-XVI is that of the polypeptide that comprises the amino acid sequence of SEQ ID NO: 16, or comprises the amino acid sequence of SEQ ID NO: 16 with substitutions, deletions, insertions or additions, or a polypeptide encoded by a polynucleotide that hybridizes under stringent conditions to a polynucleotide consisting of the nucleotide sequence of SEQ ID NO: 15. However, a polypeptide that comprises the amino acid sequence of SEQ ID NO: 16 is known in the prior art, as evidenced by Accession No. Q96CC6 (Database SWALL, Accession No. Q96CC6; Dec. 1, 2001; cited in the IDS and the International Search Report as an "X" reference). Therefore, the polypeptide of SEQ ID NO: 16 is not a special technical feature that makes a contribution over the prior art as a whole.

The technical feature of group I is: a polypeptide that that comprises the amino acid sequence of SEQ ID NO: 16, or comprises the amino acid sequence of SEQ ID NO: 16 with substitutions, deletions, insertions or additions, or a polypeptide encoded by a polynucleotide that hybridizes under stringent conditions to a polynucleotide consisting of the nucleotide sequence of SEQ ID NO: 15.

The technical feature of group II is: a polynucleotide encoding a polypeptide that comprises the amino acid sequence of SEQ ID NO: 16, or comprises the amino acid sequence of SEQ ID NO: 16 with substitutions, deletions, insertions or additions, or a polypeptide encoded by a polynucleotide that hybridizes under stringent conditions to a polynucleotide consisting of the nucleotide sequence of SEQ ID NO: 15.

The technical feature of group III is: an antibody that binds to a polypeptide that that comprises the amino acid sequence of SEQ ID NO: 16, or comprises the amino acid sequence of SEQ ID NO: 16 with substitutions, deletions, insertions or additions, or a polypeptide encoded by a polynucleotide that hybridizes under stringent conditions to a polynucleotide consisting of the nucleotide sequence of SEQ ID NO: 15.

The technical feature of group IV is: a antisense polynucleotide or small interfering RNA that inhibits expression of a polynucleotide that encodes a polypeptide that that comprises the amino acid sequence of SEQ ID NO: 16, or comprises the amino acid sequence of SEQ ID NO: 16 with

substitutions, deletions, insertions or additions, or a polypeptide encoded by a polynucleotide that hybridizes under stringent conditions to a polynucleotide consisting of the nucleotide sequence of SEQ ID NO: 15.

The technical feature of group V is: detection of mRNA encoding a polypeptide that that comprises the amino acid sequence of SEQ ID NO: 16, or comprises the amino acid sequence of SEQ ID NO: 16 with substitutions, deletions, insertions or additions, or a polypeptide encoded by a polynucleotide that hybridizes under stringent conditions to a polynucleotide consisting of the nucleotide sequence of SEQ ID NO: 15.

The technical feature of group VI is: detection of a polypeptide that that comprises the amino acid sequence of SEQ ID NO: 16, or comprises the amino acid sequence of SEQ ID NO: 16 with substitutions, deletions, insertions or additions, or a polypeptide encoded by a polynucleotide that hybridizes under stringent conditions to a polynucleotide consisting of the nucleotide sequence of SEQ ID NO: 15.

The technical feature of group VII is: detection of biological activity of a polypeptide that that comprises the amino acid sequence of SEQ ID NO: 16, or comprises the amino acid sequence of SEQ ID NO: 16 with substitutions, deletions, insertions or additions, or a polypeptide encoded by a polynucleotide that hybridizes under stringent conditions to a polynucleotide consisting of the nucleotide sequence of SEQ ID NO: 15.

The technical feature of group VIII is: use of a polypeptide that that comprises the amino acid sequence of SEQ ID NO: 16, or comprises the amino acid sequence of SEQ ID NO: 16 with substitutions, deletions, insertions or additions, or a polypeptide encoded by a polynucleotide that hybridizes under stringent conditions to a polynucleotide consisting of the nucleotide sequence of SEQ ID NO: 15 to screen for compounds useful in treating cancer.

The technical feature of group IX is: use of a cell expressing a polynucleotide comprising SEQ ID NO: 15 to screen for compounds useful in treating cancer.

The technical feature of group X is: use of a cell comprising a vector comprising a regulatory region of a gene encoding for a polypeptide that that comprises the amino acid sequence of SEQ ID NO: 16, or comprises the amino acid sequence of SEQ ID NO: 16 with substitutions, deletions, insertions or additions, or a polypeptide encoded by a polynucleotide that hybridizes under stringent conditions to a polynucleotide consisting of the nucleotide sequence of SEQ ID NO: 15 to screen for compounds useful in treating cancer.

The technical feature of group XI is: administering an antibody that binds to a polypeptide that that comprises the amino acid sequence of SEQ ID NO: 16, or comprises the amino acid sequence of SEQ ID NO: 16 with substitutions, deletions, insertions or additions, or a polypeptide encoded by a polynucleotide that hybridizes under stringent conditions to a polynucleotide consisting of the nucleotide sequence of SEQ ID NO: 15

The technical feature of group XII is: administering a compound selected from the method of claim 17.

The technical feature of group XIII is: administering a compound selected from the method of claim 14.

The technical feature of group XIV is: administration of a polypeptide that that comprises the amino acid sequence of SEQ ID NO: 16, or comprises the amino acid sequence of SEQ ID NO: 16 with substitutions, deletions, insertions or additions, or a polypeptide encoded by a polynucleotide that hybridizes under stringent conditions to a polynucleotide consisting of the nucleotide sequence of SEQ ID NO: 15 to generate an immune response.

The technical feature of group XV is: administering a polynucleotide encoding a polypeptide that that comprises the amino acid sequence of SEQ ID NO: 16, or comprises the amino acid sequence of SEQ ID NO: 16 with substitutions, deletions, insertions or additions, or a polypeptide encoded by a polynucleotide that hybridizes under stringent conditions to a polynucleotide consisting of the nucleotide sequence of SEQ ID NO: 15 to generate an immune response.

The technical feature of group XVI is: administering antigen presenting cells that have been incubated with a polypeptide that that comprises the amino acid sequence of SEQ ID NO: 16, or comprises the amino acid sequence of SEQ ID NO: 16 with substitutions, deletions, insertions or additions, or a polypeptide encoded by a polynucleotide that hybridizes under stringent conditions to a polynucleotide consisting of the nucleotide sequence of SEQ ID NO: 15.

Applicant is advised that the reply to this requirement to be complete must include (i) an election of a species or invention to be examined even though the requirement be traversed (37 CFR 1.143) and (ii) identification of the claims encompassing the elected invention.

The election of an invention or species may be made with or without traverse. To reserve a right to petition, the election must be made with traverse. If the reply does not distinctly and specifically point out supposed errors in the restriction requirement, the election shall be treated as an election without traverse.

Should applicant traverse on the ground that the inventions or species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the inventions or species to be obvious variants or clearly admit on the record that this is the case. In

either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C.103(a) of the other invention.

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Anne Holleran, whose telephone number is (571) 272-0833. The examiner can normally be reached on Monday through Friday from 9:30 am to 5:00 pm. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Larry Helms, can be reached on (571) 272-0832. Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the Group receptionist whose telephone number is (571) 272-1600.

Papers related to this application may be submitted to Group 1600 by facsimile transmission. The faxing of such papers must conform to the notice published in the Official Gazette, 1096 OG 30 (November 15, 1989). The Official Fax number for Group 1600 is (571) 273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished

applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll free).

Anne L. Holleran
Patent Examiner
April 16, 2007

LARRY R. HELMS, PH.D.
SUPERVISORY PATENT EXAMINER